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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,419	11/12/2003	Jingkun Li	19596-0551 (45738-294417)	7609

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/712,419	LI, JINGKUN
	Examiner	Art Unit
	Bao-Thuy L. Nguyen	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16 and 20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-16 and 20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 May 2006 has been entered.

2. Claims 26—30 have been added. Claims 11-16 and 21-25 were previously withdrawn. However, since these claims have now been amended to depend on claim 1, the election/restriction is withdrawn and claims 11-16 and 21-25 are hereby rejoined. Claims 1-7, 9-16 and 20-30 are pending.

3. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

4. The text of those US codes not found in this office action may be found in a previous action.

Claim Rejections - 35 USC § 112

5. Claims 21, 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is missing an "and" between the last two members of the Markush group.

The preamble of claim 26 does not correlate with the steps of the claim. The preamble does not recite the proliferation, replication or reproduction of the analyte.

Claim Rejections - 35 USC § 102

6. Claims 9-10 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noda et al (US 5,900,379).

Claims 9-10 and 20 are directed to a device and kit comprising the device having a plurality of zones, one of which is "capable of" being separated from the other zones of the device.

Noda discloses such a device and kit. Noda teaches a test kit comprising a lateral flow device having a section that is removable. The removable section comprises a capture region where immobilized antibodies are used to capture an analyte. See column 5, lines 35-44; and column 11, example 1. Noda teaches a variety of analytes that can be detected including infectious disease agents (bacterial or vial) such as Streptococcus, Neisseria and Chlamydia. See column 6, lines 48-51.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-7, 9-16 and 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBorde (US 6,607,922) in view of Benjamin et al (US 5,491,068).

LaBorde discloses and immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analytes in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis by appropriate means. See column 2, lines 5-15; column 3, lines 13-30; and column 4, lines 13-17. LaBorde teaches that the removable test strip is stable and can be achieved either before or after being read. The analytes contained in the capture zone remain there, labeled with the conjugate combination. See column 5, lines 48-63. Even though LaBorde does not specifically teach a test kit comprising such a device, LaBorde anticipates the instant kit claim because it is nothing more than the device itself with no additional components.

LaBorde differs from the instant invention in failing to teach the detection of microorganism and growing the captured organisms in appropriate media to cause the proliferation thereof.

Benjamin discloses a method comprising contacting a sample with magnetic solid support beads having antibodies immobilized thereon. If present, the target-selected bacteria cells binds to the antibodies and the beads with attached immobilized

bacteria are then washed to remove any remaining sample. The beads with the immobilized bacterial are spread on a culture medium and the bacteria are allowed to grow to form colonies. To confirm that the colonies are the bacterial of interest, the colonies are contacted with a colony lift membrane, and the membrane can be subjected to several detection/analytical procedures by which the presence or characteristics of the bacteria are determined. See column 4, lines 6-63. The analytes taught by Benjamin comprises food contaminants such as pathogenic bacteria and other well known bacterial contaminants. See column 1, lines 25-32. Benjamin also teaches analyzing microorganisms using PCR techniques. See column 3 lines 40-52.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the capture portion of LaBorde in a culture medium to increase the quantity of the analyte such as taught by Benjamin because Benjamin teaches that capture particles such as magnetic beads facilitate the capturing, isolating and enriching of microorganisms in order to accurately identify and study them, and a skilled artisan would have had a reasonable expectation of success in placing the capture portion of LaBorde in the grow medium taught by Benjamin.

Response to Arguments

9. Applicant's arguments filed 02 May 2006 have been fully considered but they are not persuasive.

Applicant argues that the instant claim differ from Noda because Noda fails to teach that the membrane immunoassay (detection zone) is entirely separatable from the remainder of the cassette or cassette support means.

This argument is not persuasive. Noda anticipates claims 9, 10 and 20 which are directed to a device and kit comprising the device. The device comprises a plurality of zones, where at least one zone is a detection zone. The detection zone is recited as being *capable of* being separated from the plurality of zones and the remainder of the device. The recitation of intended use before and after this zone is removed does not have positive limitation of the device nor the kit.

Noda discloses each and every limitation of the claimed device and kit. The device of Noda has a plurality of zones where at least one zone is a detection zone. The detection zone is perfectly *capable of* being separated from the other zones and the remainder of the device, i.e. the casing. Whether one removes the other zones from the detection zone or vice versa, the end result is the same, i.e. a detection zone that is separated from other zones of the device. The argument that Noda does not teach that the detection zone is entirely separable from the remainder of the cassette or cassette support means is not persuasive because the claims do not exclude the cassette or cassette support means. The "device" of the instant claim is seen to be equivalent to the casing of the Noda, therefore, the when the cassette or cassette support means holding the detection zone is removed from the casing, this limitation is met.

The argument that Noda does not anticipate claim 1 is not persuasive because Noda is applied against independent claims 9, 10 and 20.

The argument that claims 10 has been amended to recite that the analyte is an organism and that the detection zone of the device is separated from the remainder of the device is not persuasive.

The analyte is not part of the device of claim 10. The recitation of intended use does not structurally alter the device of claim 10. However, the device of Noda is also recited to be capable of detecting microorganisms such as bacteria and viruses. See column 6, lines 48-51.

The argument that LaBorde teaches the removal of the *entire test strip and not the detection zone* is not persuasive.

The *entire test strip* of LaBorde consists of the *detection zone.* The sample pad 17 and wicking pad 18 are not part of the test strip but are part of the larger device. LaBorde specifically teaches removing the test strip from the support member 11, and from sample pad 17 and wicking pad 18. Therefore, LaBorde clearly anticipates the instant claims where the *capture zone* is removed from the remainder of the device (support 11 and backing 12) and the other zones. See column 5, lines 25-39.

The argument that LaBorde does not anticipate claim 9 because LaBorde does not specifically teach a kit is not persuasive. The kit of claim 9 has nothing more than a device which is taught by LaBorde. Therefore, LaBorde anticipates claim 9.

The argument that Benjamin does not remedy the deficiency of LaBorde because neither Benjamin nor LaBorde teach or suggest removal of a detection zone from a test strip is not persuasive.

As stated above, LaBorde clearly teaches separating the membrane having the detection zone from the support member 11, the sample pad 17 and the wicking pad 18. LaBorde differs from the instant claims in failing to specifically teach growing the capture analyte in appropriate media to cause the proliferation thereof. However, Benjamin teaches such a step. Benjamin teaches that analytes captured using magnetic beads such as those disclosed by LaBorde are subsequently spread on a culture medium, and the bacteria are allowed to grow to form colonies so that additional assessments on the colonies to further characterized the analyte can be made. Therefore, a skilled artisan would have had a reasonable expectation of success in placing the capture zone of LaBorde in a culture medium to increase the quantity of the analyte such as taught by Benjamin because Benjamin teaches that capture particles such as magnetic beads facilitate the capturing, isolating and enriching of microorganisms in order to accurately identify and study them.

The argument that LaBorde does not teach the removal of the protective surface on the membrane is not persuasive because the instant claims do not exclude such a protective membrane. Furthermore, LaBorde recites the criticality of the protective surface only during the detection step. Nowhere in this reference is there a teaching that the protective surface cannot be removed from the detection zone.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/29/06